IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

RECKITT BENCKISER PHARMACEUTICALS, INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC,	)	
Plaintiffs,	)	Civ. No.: 5:13-cv-00760-BO
v.	)	
BIODELIVERY SCIENCES INTERNATIONAL, INC.,	)	
Defendant.	)	

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS THE COMPLAINT

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I. INTRODUCTION

Plaintiffs Reckitt Benckiser Pharmaceuticals Inc. ("RBP"), RB Pharmaceuticals Limited ("RBP UK"), and MonoSol Rx, LLC ("MonoSol") (collectively, "Plaintiffs") respectfully submit this memorandum in opposition to Defendant BioDelivery Sciences International, Inc.'s ("BDSI") motion to dismiss the complaint.

Standing

The patent-in-suit, U.S. Patent No. 8,475,832 ("the '832 patent"), which is owned by Plaintiff RBP UK, covers the commercial opioid addiction treatment product, Suboxone® sublingual film, that is sold by Plaintiff RBP and manufactured by Plaintiff MonoSol. Plaintiffs each have standing to assert the '832 patent, RBP UK as the patent owner and RBP and MonoSol as exclusive licensees. RBP UK and RBP have the same parent company. RBP holds the New Drug Application (NDA) for Suboxone® sublingual film, and, since that NDA was approved by the FDA, RBP has been, with the knowledge of RBP UK, the exclusive seller and distributor of that product in the U.S. In addition to having this implied license from its sister company, RBP and RBP UK have memorialized RBP's exclusive rights under the '832 patent in a license, a copy of which is attached as Confidential Exhibit A.

For its part, Plaintiff MonoSol, which licensed certain pharmaceutical film technology rights to RBP, has pursuant to a license, supply, and manufacturing agreement, the exclusive right to manufacture Suboxone® sublingual film for RBP. (A copy of that agreement is attached as Confidential Exhibit B). Under Federal Circuit and district court precedent, it is clear that each of the Plaintiffs has standing under these facts. Thus, BDSI's motion to dismiss for lack of standing should be denied.

Failure to State a Claim

BDSI's motion to dismiss Plaintiffs' infringement count under 35 U.S.C. § 271(e)(2) (Count II), for failure to state a claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure, should also be rejected. The Federal Circuit's 2012 decision in *AstraZeneca*, as expressly recognized in subsequent district court decisions, makes clear that subject matter jurisdiction exists over Plaintiffs' § 271(e)(2) count and that Plaintiffs state a viable § 271(e)(2) claim. Refusing to acknowledge the import of these decisions, BDSI inappositely relies on pre-*AstraZeneca* cases and fails to confront the fact that, under the governing law, Plaintiffs state a viable claim under § 271(e)(2) because BDSI's 505(b)(2) NDA seeks approval of a drug (Bunavail™) that is covered by the claims of the asserted patent or the use of which is claimed in the asserted patent. Accordingly, BDSI's motion to dismiss Count II should be denied.

Declaratory Judgment Jurisdiction

Furthermore, there is ample support for subject matter jurisdiction over Plaintiffs' declaratory judgment count of infringement under 35 U.S.C. § 271(a)-(c) (Count I). BDSI's own actions and statements demonstrate that a real and immediate controversy exists between the parties. BDSI submitted its 505(b)(2) application for Bunavail™, for the specific purpose of obtaining FDA approval to enter the market with a competing version of Plaintiffs' Suboxone® sublingual film product, before the expiration of the asserted patent. BDSI has repeatedly stated that FDA approval of its 505(b)(2) application for Bunavail™ is imminent (this June),and that BDSI is ready and intends to enter the market immediately thereafter. *See, e.g.*, D.I. 1, Compl. ¶ 34; BDSI's Jan. 10, 2014 Press Release, attached as Exhibit C ("As previously reported, the U.S. Food and Drug Administration (FDA) has assigned a Prescription Drug User Fee Act (PDUFA) date of ***June 7, 2014*** for BUNAVAIL, which if approved is anticipated to

launch late third quarter 2014.") (emphasis added). This press release, issued weeks after the commencement of this action, makes it abundantly clear that BDSI intends to launch at-risk later this year.

The parties' long adversarial history further confirms that an actual controversy exists. The parties are or were involved in several disputes including: Citizen Petitions relating to BDSI's 505(b)(2) application for Bunavail™, before the FDA; and a pending action before the U.S. District Court for the District of New Jersey, relating to BDSI's Onsolis™ film product. Just recently, on January 15, 2014, BDSI challenged the validity of the '832 patent and filed a petition to institute an *inter partes* review with the United States Patent and Trademark Office ("USPTO").

Thus, there is a real and immediate controversy between Plaintiffs and BDSI that fully warrants the Court's exercise of its declaratory judgment jurisdiction.

II. NATURE AND STAGE OF THE PROCEEDINGS

This is an action for infringement of the '832 patent. The complaint includes a declaratory judgment of infringement count under 35 U.S.C. § 271(a)-(c) (count I) and a patent infringement count under 35 U.S.C. § 271(e)(2) (count II). D.I. 1, Compl.

On December 13, 2013, BDSI moved to dismiss the complaint, for lack of standing under Rule 12(b)(1), for lack of subject matter jurisdiction under Rule 12(b)(1) over count I, and for failure to state a claim under Rule 12(b)(6) in connection with count II. (D.I. 18.) On December 31, 2013, this Court granted Plaintiffs' request for an extension of time to January 22, 2014, to respond to BDSI's motion to dismiss.

Plaintiffs respectfully request that this Court deny in its entirety BDSI's motion to dismiss the complaint.

III. STATEMENT OF FACTS

This action arises from BDSI's filing of an NDA under 21 U.S.C. § 355(b)(2) (the "505(b)(2) application") with the United States Food and Drug Administration ("FDA"), seeking approval, before the expiration of Plaintiffs' asserted patent, to manufacture and sell a competing pharmaceutical drug product to Suboxone® film that contains the same active ingredients, and is intended to treat the same medical indications (the treatment of addiction to opioids). (D.I. 1, Compl. ¶ 3.) BDSI intends to market its competing product under the name Bunavail™. *Id.*

On August 30, 2010, the FDA approved Plaintiffs' NDA No. 22-410 for the manufacture, marketing, and sale of Suboxone® sublingual film for the maintenance treatment of opioid dependence. *Id.* at ¶ 14. Plaintiffs have sold Suboxone® sublingual film since its approval. *Id.* The '832 patent is listed in the Orange Book as covering Suboxone® sublingual film. *Id.* at ¶ 18. Plaintiff RBP also owns NDA No. 20-733 for Suboxone® sublingual tablet. *Id.* at ¶ 15. Suboxone® sublingual tablet contains the same active ingredients as Suboxone® sublingual film (buprenorphine hydrochloride and naloxone hydrochloride). *Id.* Suboxone® sublingual film incorporates a novel drug delivery system, i.e., pharmaceutical film technology, to treat opioid dependence. *Id.* at ¶ 2. Suboxone® sublingual film is a highly successful product, which according to BDSI itself, enjoys over a billion dollars in U.S. sales per year. *Id.* at ¶ 32.

On October 29, 2013, Plaintiffs filed a Complaint in this action. The complaint includes two counts. Count I is based upon 35 U.S.C. § 271(a)-(c) and is premised upon BDSI's stated intention to engage in the manufacture, offer for sale, sale, marketing, distribution, and/or importation of a competing film product immediately following approval of its 505(b)(2) application. (*Id.* at ¶¶ 42-49.) Count II is based upon 35 U.S.C. § 271(e)(2) and arises from BDSI's filing of its 505(b)(2) application. (*Id.* at ¶¶ 50-52.) On December 13, 2013, BDSI filed a motion to dismiss the complaint, for lack of standing under Rule 12(b)(1), for lack of subject

matter jurisdiction under Rule 12(b)(1) over count I, and for failure to state a claim under Rule 12(b)(6) in connection with count II.

Plaintiffs have standing to assert the ’832 patent. RBP UK and RBP share the same parent company, Reckitt Benckiser Group plc. RBP UK owns the ’832 patent. *Id.* at ¶ 12. RBP is the holder of NDA No. 22-410 for Suboxone® sublingual film, *id.* at ¶ 13, and, with RBP UK’s knowledge, has marketed and sold that product in the U.S since the FDA’s approval of the NDA on August 30, 2010. *See* Confidential Exhibit A. In addition to having this implied exclusive license under the ’832 patent to sell Suboxone® film, RBP UK and RBP have recently memorialized RBP’s exclusive rights under the ’832 patent in a license, a copy of which is attached as Confidential Exhibit A. For its part, MonoSol, under a Commercial Exploitation Agreement dated August 15, 2008, has an express exclusive right to manufacture Suboxone® sublingual film for RBP and is thus an implied, exclusive licensee (for manufacturing) under the ’832 patent. *See* Confidential Exhibit B.

BDSI has been actively taking steps to prepare and launch its Bunavail™ product. On July 31, 2013, Defendant BDSI submitted its 505(b)(2) application to the FDA, seeking approval to engage in the commercial manufacture and/or sale of Bunavail™. *Id.* at ¶ 24. Although the most similar alternative to Defendant BDSI’s Bunavail™ film product is Suboxone® sublingual film (NDA No. 22-410), BDSI’s 505(b)(2) application uses Suboxone® sublingual tablet (NDA No. 20-733) as the reference drug. *Id.* at ¶ 25. BDSI’s decision to use Suboxone® tablet as the reference drug instead of Suboxone® film was merely an attempt to avoid providing RBP with a Paragraph IV certification to the ’832 patent, thereby preventing RBP from filing an infringement action within 45 days of receiving the notice of Paragraph IV certification and

obtaining a 30-month injunction against BDSI, as permitted under 21 U.S.C. § 355(c)(3)(C). *Id.* at ¶ 28.

In its 2012 annual report, BDSI indicated that it "remain[ed] on track to file the NDA for BUNAVAIL™ with the U.S. Food and Drug Administration (FDA) in mid-summer 2013, putting BDSI in the position to introduce the next branded transmucosal buprenorphine/naloxone film into the marketplace for opioid dependence." D.I. 1, Compl. ¶ 32. Just recently, BDSI confirmed that "[a]s previously reported, the U.S. Food and Drug Administration (FDA) has assigned a Prescription Drug User Fee Act (PDUFA) date of June 7, 2014 for BUNAVAIL, which if approved is anticipated to launch late third quarter 2014." *See* BDSI's Jan. 10, 2014 Press Release, attached as Exhibit C.

Finally, the parties are or were involved in several disputes, including: Citizen Petition disputes before the FDA in connection with BDSI's 505(b)(2) application, starting even before BDSI filed its 505(b)(2) application, D.I. 1, Compl. ¶¶ 29-31; and a pending dispute before the U.S. District Court for the District of New Jersey in connection with BDSI's Onsolis™ film product which, like Bunavail™, also uses BDSI's BioErodible MucoAdhesive drug delivery film technology, *id.* at ¶¶ 36-40. Just recently, on January 15, 2014, BDSI also challenged the validity of the '832 patent and filed a petition to institute an *inter partes* review with the USPTO (Case No. IPR2014-00325).

IV. ARGUMENT

A. RBP Has Standing

Because there is no dispute that Plaintiff RBP UK is and was at all relevant times the owner of the '832 Patent (Op. Br. at 4) and thus has standing to sue, there is also no dispute that this suit was properly commenced. RBP UK and RBP are both subsidiaries of the same parent company, Reckitt Benckiser Group plc. *See* Confidential Exhibit A. RBP is the holder of New

Drug Application ("NDA") No. 22-410 for Suboxone® sublingual film, and has marketed and sold that product in the U.S since the FDA's approval of the NDA on August 30, 2010, and has done so with the knowledge of its affiliated company, RBP UK. *Id.* at ¶ 13. Upon issuance, RBP listed the patent-in-suit, the '832 Patent, in the FDA's "Orange Book" as covering its Suboxone® sublingual film product. Thus, at all relevant times, RBP has been at least an implied exclusive licensee in the U.S. of RBP UK with respect to the '832 Patent.

Moreover, Federal Circuit law is clear that an exclusive licensee has standing to sue for infringement as co-plaintiff with the patent owner, and that where the patent owner is party to the lawsuit, such a license may be implied. *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1552 (Fed. Cir. 1995) (*en banc)* ("To be an exclusive licensee for standing purposes, a party must have received, not only the right to practice the invention within a given territory, but also the patentee's express or implied promise that others shall be excluded from practicing the invention within that territory as well."); *Aspex Eyewear, Inc. v. Altair Eyewear, Inc.*, 288 Fed. Appx. 697, 706, 2008 WL 2950997 (Fed. Cir. 2008) (unpublished) ("[W]e hold that an exclusive license need not be in writing for the licensee to have standing if the patentee or assignee is also joined.") (attached as Exhibit D); *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharmaceuticals Inc.*, USA, 07-CV-5855 (DMC-JAD), 2011 WL 2609855, *4 (D.N.J. June 30, 2011) (unpublished) (holding plaintiffs were exclusive licensees based on implied promise and because they were the only parties practicing the patent in the United States, even though exclusive nature of license was undocumented) (attached as Exhibit E). Finally, subsequent to the commencement of this action, RBP and RBP UK memorialized RBP's exclusive license in the U.S. under the '832 Patent (a copy of which is attached as Confidential Exhibit A), and the effective date of that agreement is July 2, 2013, which is the date of issuance of the '832 Patent.

Accordingly, for all these reasons, it is undisputed that RBP UK had standing to commence this action and the governing case law makes clear that RBP had standing as well to join RBP UK as a plaintiff.

B. MonoSol Is an Exclusive Licensee and Has Standing to Assert the '832 Patent against BDSI.

Clear Federal Circuit precedent demonstrates that MonoSol has standing to assert the '832 patent. MonoSol holds the exclusionary right to manufacture the patented products. As an exclusive licensee of the asserted '832 patent, MonoSol has standing and may join the patent owner in a patent infringement litigation against BDSI.

"[T]he touchstone of constitutional standing in a patent infringement suit is whether a party can establish that it has an exclusionary right in a patent that, if violated by another, would cause the party holding the exclusionary right to suffer legal injury." *WiAV Solutions LLC v. Motorola, Inc.*, 631 F.3d 1257, 1265 (Fed. Cir. 2010). "If the accused neither possesses nor can obtain such a license, the exclusive licensee's exclusionary rights with respect to that accused party are violated by any acts of infringement that such party is alleged to have committed, and the injury predicate to constitutional standing is met." *Id.* at 1267.

"[A]n exclusive licensee may join an infringement suit as co-plaintiff with the patentee." *Abbott Laboratories v. Diamedix Corp.*, 47 F.3d 1128, 1131 (Fed. Cir. 1995) (citing *Arachnid, Inc. v. Merit Indus., Inc.*, 939 F.2d 1574, 1579 & n. 7 (Fed. Cir. 1991)).[1] In fact, "[a]n exclusive licensee generally must join the patent owner to the suit to satisfy prudential standing constraints." *WiAV*, 631 F.3d at 1265 n.1. *See also My First Shades v. Baby Blanket Suncare*, 914 F. Supp. 2d 339, 344 (E.D.N.Y. 2012) ("Courts have interpreted the Patent Act to confer

[1] A single patent can have multiple exclusive licensees. *See, e.g., Int'l Gamco, Inc. v. Multimedia Games, Inc.*, 504 F.3d 1273 (Fed. Cir. 2007). For instance, an exclusive license can be based on geographic, time, or field of use limitations. *See Amgen, Inc. v. Chugai Pharm. Co.*, 808 F. Supp. 894, 900 (D. Mass. 1992).

standing to not only patent owners but any party with some substantial rights to the patent (including parties with less than all substantial rights), as long as the title holder of the patent is joined.") (citations omitted).

The Federal Circuit held that a party is an exclusive licensee and has standing if it holds "any of the exclusionary rights." *WiAV*, 631 F.3d at 1266-67. *See also Amgen, Inc. v. Chugai Pharm. Co.*, 808 F. Supp. 894, 900 (D. Mass. 1992) ("A licensee can be deemed exclusive where the license pertains to less than all three of the rights [(manufacture, use, and sale)] granted under the patent."). "A licensee with only the exclusive right to manufacture has standing as well." *Abbott Labs v. Sandoz, Inc.*, No. 05 C 5373, 2010 WL 1948185, *3 (N.D. Ill. May 12, 2010) (unpublished) (citing *Seiko Epson Corp. v. Print–Rite Holdings, Ltd.*, No. CV 01-500-BR, 2005 WL 1231240, at *3 (D. Or. May 23, 2005)) (attached as Exhibit F). Furthermore, "an exclusive license can be created by a grant of exclusivity based solely on geographic, time, or field-of-use limitations." *Amgen*, 808 F. Supp. at 900. Unlike an assignment of all substantial rights in a patent which must be in writing, an exclusive "license may be written, verbal, or implied." *Aspex Eyewear, Inc. v. Miracle Optics, Inc.*, 434 F.3d 1336, 1339 (Fed. Cir. 2006).

MonoSol has the exclusive right to manufacture the patented product, namely, Suboxone® sublingual film. Under Federal Circuit precedent, MonoSol is an exclusive licensee and has standing to assert the '832 patent. *WiAV*, 631 F.3d at 1266-67. *See also Amgen*, 808 F. Supp. at 900 ("[A]n exclusive license can be created by a grant of exclusivity based solely on geographic, time, or field of use limitations."); *Sanofi-Aventis*, 2011 WL 2609855, *4 (D.N.J. June 30, 2011); *Abbott Labs*, 2010 WL 1948185, *3 ("A licensee with only the exclusive right to manufacture has standing as well.").

On its face, the Complaint alleges that:

> Plaintiff RBP UK is the lawful owner of the '832 patent. The '832 patent, entitled "Sublingual and Buccal Film Compositions," was duly and legally issued on July 2, 2013, to Garry L. Myers, Samuel D. Hilbert, Bill J. Boone, B. Arlie Bogue, Pradeep Sanghvi, and Madhusudan Hariharan as inventors. The named inventors assigned their rights to MonoSol, who subsequently assigned its rights in the '832 patent to Reckitt Benckiser Healthcare (UK) Limited, which then assigned its rights to RBP UK. *MonoSol manufactures Suboxone® for the US market*. A true copy of the '832 patent is attached hereto as Exhibit A.

Complaint at ¶ 12 (emphasis added). Based on a public USPTO assignment document ("USPTO Assignment") (D.I. 19-2), BDSI argues that MonoSol has no standing because it assigned its rights to Reckitt Benckiser Healthcare (UK) Limited. The USPTO Assignment, however, does not negate that an express or implied exclusive license exists conferring standing on MonoSol.

Additional obligations and consideration underlying the USPTO Assignment are outlined, *inter alia*, in a Commercial Exploitation Agreement dated August 15, 2008 between MonoSol and RBP. *See* Confidential Exhibit B. *See e.g., id.* at section 15.5 regarding intellectual property rights that arise during the term of the Agreement. MonoSol retains the exclusive right to manufacture and supply RBP's requirements of the Products. *See id.* at section 3.1 and sections 6.5 and 6.8. Further, while MonoSol, at the request of RBP, assigned its rights in the '832 patent to Reckitt Benckiser Healthcare (UK) Limited, which then assigned the rights to RB Pharmaceuticals Limited, both entities are Affiliates (a defined term) of RBP and are bound to MonoSol's exclusive manufacturing rights under the Commercial Exploitation Agreement. *See id.* at section 15.15.

One or more claims of the '832 patent cover Suboxone film (the active ingredients in which are buprenorphine and naloxone) and such a film composition falls within the scope of the "Products" (a defined term) which are the subject of the Commercial Exploitation Agreement and which MonoSol has the exclusive right to make. Therefore, MonoSol has an exclusive,

express or implied, license under the '832 patent.[2]

BDSI's accused Bunavail™ product infringes one or more claims of the '832 patent. Further, the accused infringing products compete with Suboxone® and will correspondingly reduce RBP's requirements and its Product orders to MonoSol. Thus, MonoSol will be directly injured by BDSI's sale of the Bunavail™ product.

Thus, there is no dispute that MonoSol has standing to bring suit and to assert the '832 patent against BDSI.

C. Count II States a Viable Claim for Infringement because BDSI's Filing of Its 505(b)(2) NDA Constitutes an Act of Infringement Under § 271(e)(2).

BDSI contends that Count II of the Complaint fails to state a claim upon which relief may be granted because BDSI's 505(b)(2) NDA did not contain a Paragraph IV certification and Plaintiffs therefore allegedly have no basis to assert a claim for patent infringement under 35 U.S.C. § 271(e)(2). *E.g.*, Op. Br. at 3. As shown below, the Federal Circuit's 2012 decision in *AstraZeneca*, as expressly recognized in several subsequent district court decisions, specifically rejected that proposition, holding that a Paragraph IV certification is ***not*** a prerequisite for a § 271(e)(2) claim. And Count II does not fail to state a claim because, as required by *AstraZeneca*, it alleges that the filing of BDSI's 505(b)(2) application is an act of infringement because it seeks FDA approval to market a drug claimed in the '832 patent. Plaintiffs, upon prevailing on the merits, will be entitled to mandatory relief under § 271(e)(4). *See Research Found. of State Univ. of N.Y. v. Mylan Pharms. Inc.*, Nos. 09-184-LPS, 10-892-LPS, 2012 U.S. Dist. LEXIS 80737, at *14 (D. Del. 2012), *aff'd in relevant part*, *Research Found. of State Univ. of N.Y. v.*

[2] MonoSol's license is not a bare license. *See WiAV*, 631 F.3d at 1265 ("[A] so-called "bare licensee" holds nothing more than a promise from the patentee that the patentee will not sue the licensee for practicing the patented invention."). *See also My First Shades v. Baby Blanket Suncare*, 914 F. Supp. 2d at 348.

Mylan Pharms. Inc., No. 2012-1523, 2013 U.S. App. LEXIS 16284, at *3 (Fed. Cir. 2013) (unpublished) (attached as Exhibit G).

1. It Is Undisputed that the Court Has Subject Matter Jurisdiction over Count II.

BDSI relies on the fact that it has not filed a Paragraph IV certification against the '832 patent. Op. Br. *passim*. However, under recent controlling Federal Circuit precedent, this is wholly irrelevant to the present motion. The plain language of § 271(e)(2) makes the filing of an ANDA or 505(b)(2) application an act of infringement of a patent covering the proposed drug and/or its use and does not require that there be a Paragraph IV certification:

> It shall be an act of infringement to submit—
>
> (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,
>
> . . .
>
> if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

It is true that, prior to the Federal Circuit's decision in *AstraZeneca Pharms. LP v. Apotex Corp*., 669 F.3d 1370 (Fed. Cir. 2012), some district courts held that a Paragraph IV certification was a jurisdictional requirement for a patentee to bring an infringement claim under the Hatch-Waxman Act, i.e., under § 271(e)(2). But that is not the law, as *AstraZeneca* "resolved any doubt on this issue." *Takeda Pharm. Co., LTD v. Handa Pharms., LLC*, No. C-11-00840-JCS, 2013 U.S. Dist. LEXIS 74126, at *60 (N.D. Cal. 2013) (unpublished) (also reviewing previous District Court cases to the contrary) (attached as Exhibit H). "[T]he Supreme Court also made clear that a Paragraph IV certification is not a jurisdictional requirement for bringing an action

under the Hatch-Waxman Act." *Id.* at *61 (citing *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670 (2012)).

Evaluating a brand patentee's § 271(e)(2) claim in the absence of a Paragraph IV certification, the Federal Circuit held in *AstraZeneca* that, under the Hatch-Waxman Act, "the requirements for jurisdiction in the district courts are met once a patent owner alleges that another's filing of an ANDA [or 505(b)(2) NDA][3] infringes its patent under § 271(e)(2)." *AstraZeneca*, 669 F.3d at 1377. Thus, as District Courts have recognized, in *AstraZeneca* "the Federal Circuit held that a Paragraph IV certification was ***not*** required for subject matter jurisdiction over a patentee's § 271(e)(2) claims." *Research Found.*, 2012 U.S. Dist. LEXIS at *13 (emphasis added) (Ex. G); *see also Takeda*, 2013 U.S. Dist. LEXIS at *63-64 (collecting cases) (Ex. H).

BDSI acknowledges that it does not challenge this Court's subject matter jurisdiction over Count II because *AstraZeneca* "clarified that Courts do not lack subject matter jurisdiction over claims for patent infringement [allegedly] improperly brought pursuant to 271(e)(2)." Op. Br. at 18 n.4; *see also, e.g.*, 19 (not alleging lack of subject matter jurisdiction as to Count II). Despite this recognition, BDSI inexplicably repeatedly quotes ***pre***-*AstraZeneca* district court cases requiring that a "Paragraph IV Certification must be filed . . . to confer jurisdiction." *E.g.*, Op. Br. at 6, 17, 19.

For instance, BDSI extensively cites two unpublished ***pre***-*AstraZeneca* District of New Jersey cases holding that "to establish an act of infringement pursuant to § 271(e)(2), the [application] must contain a Paragraph IV certification against a patent listed in the Orange Book for the drug in question." Op. Br. at 17, 19. BDSI fails to mention that the ***same*** District Court

[3] Section 271(e)(2) makes no distinction between ANDAs and 505(b)(2) NDAs, nor does BDSI allege that there is any such difference.

revisited the issue last year in another unpublished decision and came to the opposite conclusion ***post***-*AstraZeneca*. The Court discussed the two opinions BDSI cites (*Eisai* and *Novo Nordisk*), and ***denied*** a motion to dismiss, explaining that, in the intervening *AstraZeneca* decision, the "Federal Circuit recently rejected the argument by a generic drug company that '§ 271(e)(2) creates a case or controversy only if the accused ANDA contains a Paragraph IV certification.'" *Merck Sharp & Dohme Corp. v. Sandoz Inc*., 2013 U.S. Dist. LEXIS 19933, at *9 (D.N.J. 2013) (unpublished) (attached as Exhibit I).

AstraZeneca and the subsequent cases following it state the governing law. This Court should disregard BDSI's misleading citations to opinions contradicted by subsequent controlling Federal Circuit precedent and repudiated, post-*AstraZeneca*, by some of those same courts. BDSI cites no case to the contrary after *AstraZeneca* and Plaintiffs are aware of none. *AstraZeneca*, as recognized by the subsequent district court decisions discussed above, conclusively establishes that a Paragraph IV certification is not necessary for a § 271(e)(2) claim.[4]

2. Count II States a Viable Claim that BDSI's 505(b)(2) Application Infringes the Composition and Method-of-Use Claims of the '832 Patent.

Having conceded subject matter jurisdiction, as it must, BDSI tries to fit its attack on Count II within the framework of *AstraZeneca*. According to BDSI, *AstraZeneca* clarified that "misplaced" § 271(e)(2) claims "simply fail to state a claim upon which relief may be granted pursuant to FRCP 12(b)(6)." Op. Br. at 18 n.4. But *AstraZeneca* itself demonstrates that there is

[4] BDSI also alleges that permitting Plaintiffs' § 271(e)(2) claim to proceed without a Paragraph IV certification would be inconsistent with the FDA's decision on Plaintiffs' Citizen Petitions, declining to refuse to file BDSI's 505(b)(2) application without such a Paragraph IV certification. Op. Br. at 18. Plainly, the FDA's statements concern its own review processes and have no bearing on whether Count II is properly in front of this Court, which is determined by the patent laws and the federal jurisdictional statutes. BDSI's quarrel is with the Federal Circuit's interpretation of those laws.

nothing "misplaced" about Plaintiffs' Count II. In *AstraZeneca*, after finding there was jurisdiction despite the lack of a Paragraph IV certification, the Federal Circuit dismissed the patentee's method-of-use claims because ***the ANDAs expressly carved out the indications recited as the claimed uses in the patents***. Hence, the patentee had not alleged (and could not allege) that the ANDAs sought FDA approval for uses covered by the method patents at issue, "as would be required to state a viable § 271(e)(2) claim." *AstraZeneca*, 669 F.3d at 1379.

The facts presented here are diametrically opposite. In the present case, Plaintiffs allege that BDSI's 505(b)(2) application seeks approval to market a film product ***covered*** by the film composition claims of the '832 patent. Approval is sought for an indication ("treatment of opioid dependence") (Complaint ¶ 33) covered by the method of use claims (for "treating narcotic dependence") of that patent. Hence, the submission of BDSI's 505(b)(2) application was an act of infringement of the '832 patent because BDSI's purpose was to obtain approval to market a product claimed in the '832 patent and/or the use of which is claimed in the patent before the expiration of the patent. These allegations state a "viable § 271(e)(2) claim," as specifically contemplated by *AstraZeneca,* and cannot be dismissed.

BDSI argues that the reference product relied upon in BDSI's 505(b)(2) application, namely the Suboxone® tablet product, is outside the scope of the '832 patent. Op. Br. at 18. But that is irrelevant to Plaintiffs' § 271(e)(2) claim. Rather, the relevant question, largely ignored by BDSI, and according to the plain language of § 271(e)(2), is whether BDSI's 505(b)(2) application, not the reference product, covers a drug claimed in a patent or the use of which is claimed in a patent. Plaintiffs allege that BDSI's 505(b)(2) application does, and nowhere does BDSI's motion argue otherwise. Plaintiffs have pled "enough facts to state a claim to relief that

is plausible on its face." *See Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Thus, Plaintiffs state a viable § 271(e)(2) claim.

D. This Court Has Subject Matter Jurisdiction over the Declaratory Judgment Count Under § 271(a)-(c).

1. Legal Standards

Under the Declaratory Judgment Act, an actual controversy exists where the facts "show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (citations omitted). Whether a declaratory judgment action presents an actual controversy must be determined based on "all the circumstances." *Id.* A justiciable dispute must be "definite and concrete, touching the legal relations of parties having adverse legal interests, . . . real and substantial, and admit of specific relief through a decree of conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *Id.* at 127 (citations omitted).

A patentee may seek a declaration that a person will infringe a patent in the *future*. *See, e.g., Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570 (Fed. Cir. 1997) (citing *Lang v. Pacific Marine & Supply Co.*, 895 F.2d 761, 763 (Fed. Cir. 1990)) (emphasis added). The exercise of jurisdiction over such an action is within the discretion of the district court. *Id.* Declaratory judgment jurisdiction exists where: "(1) the defendant [is] engaged in an activity directed toward an infringement charge or [is] making meaningful preparation for such activity; and (2) acts of the defendant [] indicate a refusal to change the course of its actions in the face of acts by the patentee sufficient to create a reasonable apprehension that a suit will be forthcoming." *Cephalon, Inc. v. Sandoz, Inc.*, No. 11-cv-821-SLR, 2012 WL 682045, * 5 (D. Del. Mar. 1, 2012) (unpublished) (citing *Glaxo*, 110 F.3d at 1571) (attached as Exhibit J).

BDSI's motion presents a factual challenge to the Complaint. BDSI argues that Plaintiffs' claims are speculative. *See* Op. Br. at 7. Thus, this Court is not confined to the allegations in the Complaint but may consider evidence outside the pleadings to resolve factual issues bearing on the jurisdictional dispute. *See, e.g.*, *Kerns v. United States*, 585 F.3d 187, 192 (4th Cir. 2009).

2. There Is a Real and Immediate Controversy between the Parties over BDSI'S Imminent Infringement of the Asserted Patent.

BDSI's conduct clearly meets the standards for establishing declaratory judgment jurisdiction, and demonstrates that there is a real and immediate controversy. FDA approval for the Bunavail™ product is only a few months away and BDSI has repeatedly indicated that it intends to enter the market immediately thereafter.

BDSI satisfies the Federal Circuit test for declaratory judgment jurisdiction: (1) BDSI is engaged in an activity directed toward an infringement charge and has already made meaningful preparation for such activity; and (2) BDSI indicates a refusal to change the course of its actions in the face of Plaintiffs' patent infringement allegations. *See Glaxo*, 110 F.3d at 1571; *Cephalon*, 2012 WL 682045, * 5 (Ex. J).

First, BDSI submitted its 505(b)(2) application for the specific purpose of obtaining FDA approval to enter the market with a competing version of Plaintiffs' Suboxone® sublingual film product, before the expiration of the asserted patent. BDSI deliberately used the Suboxone® tablet product as the reference drug instead of Suboxone® film to avoid the '832 patent, and to prevent Plaintiffs from obtaining a 30-month stay of FDA approval, as permitted under 21 U.S.C. § 355(c)(3)(C). See D.I. 1, Compl. ¶ 28.

Further, BDSI consistently indicated that it is making meaningful progress towards market entry and that it does not intend to change course. In its 2012 annual report, BDSI

indicated that it "remain[ed] on track to file the NDA for BUNAVAIL™ with the U.S. Food and Drug Administration (FDA) in mid-summer 2013, *putting BDSI in the position to introduce the next branded transmucosal buprenorphine/naloxone film into the marketplace for opioid dependence*." D.I. 1, Compl. ¶ 32 (emphasis added). BDSI also indicated that its FDA filing would include "data from [its] positive pivotal bioequivalence study completed in the second half of 2012" and "data from the 'Suboxone conversion' safety study which completed in early 2013" and which demonstrated "favorable tolerability of BUNAVAIL™ in opioid dependent subjects when switched from Suboxone." *Id.* On July 31, 2013, BDSI submitted its 505(b)(2) application to the FDA, seeking approval to engage in the commercial manufacture and/or sale of Bunavail™. *Id at* ¶ 24. In submitting its 505(b)(2) application, BDSI was required to fully develop its Bunavail™ product, complete manufacturing control testing, and develop a proposed product label. *See* 21 C.F.R. § 314.50.

Furthermore, BDSI has now consistently indicated that FDA approval was merely few months away and that the FDA's forthcoming approval would allow BDSI's Bunavail™ product to be "the first buccal film dosage form containing buprenorphine for the treatment of opioid dependence that will compete with the market leader Suboxone . . . ." D.I. 1, Compl. ¶ 33. On August 1, 2013, BDSI's Chief Executive Officer declared that: "It is our intention to bring to market a product that we believe positions us to significantly participate in this $1.5 billion and growing market." D.I. 1-2, Compl. Ex. B. On October 9, 2013, BDSI announced that its NDA for Bunavail™ "has been accepted for filing by the [FDA]" and that "the review of the BUNAVAIL NDA is expected to be completed by early June 2014." *Id.* at ¶ 34. In a recent press release, BDSI confirmed that FDA approval was expected in June 2014, and that BDSI intends to enter the market immediately thereafter. *See* Ex. C (BDSI's Jan. 10, 2014 Press

Release) ("As previously reported, the U.S. Food and Drug Administration (FDA) has assigned a Prescription Drug User Fee Act (PDUFA) date of June 7, 2014 for BUNAVAIL, which if approved is anticipated to launch late third quarter 2014. BDSI estimates annual peak U.S. sales of BUNAVAIL of up to $250 million.").[5] BDSI's Bunavail™ product is ready and BDSI can launch any time after FDA approval. Further, BDSI has a huge incentive to be the "first" to compete with Suboxone® to "significantly participate in this $1.5 billion and growing market." D.I. 1-2, Compl. Ex. B; D.I. 1, Compl. at ¶ 32. Subject matter jurisdiction is warranted under these facts. *See Glaxo*, 110 F.3d at 1571 (affirming subject matter jurisdiction over declaratory judgment claim where "FDA approval [was] imminent"); *Cephalon*, 2012 WL 682045, * 5 (finding declaratory judgment jurisdiction where FDA approval was less than eight months away) (Ex. J); *Bayer Healthcare, LLC v. Norbrook Labs., Ltd.*, Nos. 08-C-953, 09-C-108, 2009 WL 6337911, *13-14 (E.D. Wis. Sept. 24, 2009) (unpublished) (finding declaratory judgment jurisdiction where FDA could approve the application "in the immediate future") (attached as Exhibit L).[6]

Still further, there is no question that an actual controversy exists between the parties. The parties were involved in Citizen Petition disputes before the FDA in connection with BDSI's 505(b)(2) application, starting even before BDSI filed its 505(b)(2) application. D.I. 1, Compl.

[5] While the district court in Delaware recently declined subject matter jurisdiction over Plaintiffs' declaratory judgment counts in *Reckitt Benckiser Pharmaceuticals Inc. v. Watson Laboratories., Inc.*, 1:13-cv-01674-RGA (D.I. 34, Jan. 17, 2014) (unpublished) (attached as Exhibit K), unlike the present case, FDA approval is subject to a 30-month stay in that case.

[6] These cases demonstrate that, contrary to BDSI's assertions (Op. Br. at 10, 12), neither FDA approval nor present infringement, are required for subject matter jurisdiction over a declaratory judgment count. Further, the cases cited by BDSI are inapposite because Defendant could still change course in those cases. In contrast, BDSI's Bunavail™ product is fixed and cannot be easily changed in view of FDA regulations.

¶¶ 29-31. The parties also have a pending dispute before the U.S. District Court for the District of New Jersey in connection with BDSI's Onsolis™ film product which, like Bunavail™, also uses BDSI's BioErodible MucoAdhesive drug delivery film technology. *Id.* at ¶¶ 36-40.[7] Just recently, on January 15, 2014, BDSI challenged the validity of the '832 patent and filed a petition to institute an *inter partes* review with the USPTO (Case No. IPR2014-00325), confirming that an actual controversy exists between the parties. BDSI is obviously attempting to engage in forum shopping, refusing this Court's jurisdiction and denying that a controversy exists as to the validity of the '832 patent on one hand, but on the other hand, requesting an adjudication of the validity of the '832 patent from the USPTO.

Thus, there is a real and immediate controversy between the parties and Plaintiffs should be allowed to proceed with their declaratory judgment count. By accepting declaratory judgment jurisdiction, this Court can end the controversy and bring legal certainty to the parties.

V. CONCLUSION

For all the foregoing reasons, BDSI's motion to dismiss the complaint should be denied in its entirety.

[7] Contrary to BDSI's assertions (Op. Br. at 8), these allegations are not "immaterial" but further support Plaintiffs' argument that an actual controversy exists between the parties.

This the 22nd day of January, 2014.

Respectfully submitted,
/s/ Michael E. Ray
Michael E. Ray (N.C. State Bar 8480)
WOMBLE, CARLYLE, SANDRIDGE & RICE LLP
One West Fourth Street
Winston-Salem, NC 27101
Phone: 1-336-721-3648
Fax: 1-336-733-8312
E-mail: mray@wcsr.com

Attorneys for Plaintiffs

Of Counsel:

Daniel A. Ladow
James M. Bollinger
TROUTMAN SANDERS LLP
405 Lexington Avenue
New York, NY 10174
(212) 704-6000
(212) 704-5929 (Fax)
daniel.ladow@troutmansanders.com
james.bollinger@troutmansanders.com

Troy S. Kleckley
Aaron Rugh
TROUTMAN SANDERS LLP
600 Peachtree Street, NE
Suite 5200
Atlanta, GA 30308
(404) 885-3000
(404) 885-3900 (Fax)
troy.kleckley@troutmansanders.com
aaron.rugh@troutmansanders.com

Attorneys for Plaintiffs
Reckitt Benckiser Pharmaceuticals, Inc.
and RB Pharmaceuticals Limited

Of Counsel:

James F. Hibey
Timothy C. Bickham
STEPTOE & JOHNSON LLP
1330 Connecticut Avenue, NW
Washington DC 20036
(202) 429-3000
(202) 429-3902 (Fax)
jhibey@steptoe.com
tbickham@steptoe.com

Attorneys for Plaintiff
MonoSol Rx, LLC

CERTIFICATE OF SERVICE

I hereby certify that a true and exact copy of the foregoing has been delivered via ECF to the following on this 22nd day of January, 2014:

Richard T. Matthews
Myers Bigel Sibley & Sajovec, P.A.
4140 Parklake Avenue, Suite 600
Raleigh, NC 27612
rmatthews@myersbigel.com

Daniel M. Silver
McCarter & English, LLP
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801
dsilver@mccarter.com

Lee Carl Bromberg
McCarter & English, LLP
265 Franklin Street
Boston, MA 20110
lbromberg@mccarter.com

/s/ Michael E. Ray
Womble Carlyle Sandridge & Rice, LLP
One West Fourth Street
Winston-Salem, NC 27101
Phone: 1-336-721-3648
Fax: 1-336-733-8312
mray@wcsr.com